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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,812	07/17/2003	Joachim Buenger	MERCK 2206 P1	8982

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EXAMINER

LAMM, MARINA

ART UNIT PAPER NUMBER

1617

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,812

Applicant(s)

BUENGER ET AL.

Examiner

Marina Lamm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-9,11,12 and 14-22 is/are pending in the application.
- 4a) Of the above claim(s) 1,4,7-9,12 and 15-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,6,11 and 14-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/6/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the amendment filed 9/6/06. Claims pending are 1, 3, 4, 6-9, 11, 12 and 14-22. Claims 2, 5, 10 and 13 have been cancelled. Claims 18-22 have been added. Claims 1, 4, 7-9, 12 and 15-17 have been withdrawn from consideration as directed to non-elected invention.

Election/Restrictions

1. This application contains claims 1, 4, 7-9, 12 and 15-17 drawn to an invention nonelected with traverse in Paper No. 1/9/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Double Patenting

2. The nonstatutory obviousness-type double patenting rejection of Claims 3, 6, 11 and 14 as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,060,071 ('071) in view of either Geria (US 4,992,476) or Idson ("Dry Skin Moisturizing and Emolliency", Cosmetics & Toiletries, Vol. 107, July 1992, 69-78), is maintained for the reasons of the record. New Claims 18-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,060,071 ('071) in view of either Geria (US 4,992,476) or Idson ("Dry Skin Moisturizing and Emolliency", Cosmetics & Toiletries, Vol. 107, July 1992, 69-78) for the reasons of the record. More specifically, the limitations of Claims 20-22 are taught in '071 at col. 2,

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lines 38-41 and col. 6, lines 1-12. With respect to the surfactants listed in Claims 18 and 19, these are the conventional, widely used cosmetic surfactants.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The rejection of Claims 3, 6, 11 and 14 under 35 U.S.C. 102(b) as being anticipated by the publication "RonaCare™ Ectoin The Cell Protection Factor", dated 8/2000 (hereafter "the RonaCare™ publication"), is maintained for the reasons of the record. New Claims 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by the RonaCare™ publication for the reasons of the record.

With respect to Claims 18-21, the RonaCare™ publication teaches the membrane-stabilizing effect of 1% solution of ectoin against surfactants such as sodium lauryl sulphate, cocamidopropyl betaine, alkyl polyglucoside and sodium laureth sulphate. See p. 21

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. The rejection of Claims 3, 6, 11 and 14 under 35 U.S.C. 103(a) as being unpatentable over Motitschke et al. (US 6,060,071), in view of either Geria (US 4,992,476) or Idson ("Dry Skin Moisturizing and Emolliency", Cosmetics & Toiletries, Vol. 107, July 1992, 69-78) is maintained for the reasons of the record. New Claims 18-

22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motitschke et al. in view of either Geria or Idson for the reasons of the record.

With respect to Claims 18-22, Motitschke et al. teach the limitations of Claims 20-22 are taught in '071 at col. 2, lines 38-41 and col. 6, lines 1-12. With respect to the surfactants listed in Claims 18 and 19, these are the conventional, widely used cosmetic surfactants.

Response to Arguments

7. Applicant's arguments filed 9/6/06 have been fully considered but they are not persuasive.

With respect to the priority, the Applicant argues that the priority application PCT/EP99/05239 "provides both a written description and enablement for all the claims in this application, both before and after the current amendments." See pp. 8-9 of the reply. In response, it is noted that while the priority application provides an adequate support for a method of protecting the skin of a human patient from high exogenous concentrations of sodium dodecyl sulfate (SDS) by administering to the patient a composition comprising an ectoin compound of the given formula, the priority application is silent with respect to the protection of the skin from high exogenous concentrations of surfactants other than SDS, which is the subject matter of the instant claims. While broadly disclosing protecting skin "against damage as a result of drying out and the withdrawal of water" or "from high salt concentration of the skin", the priority application does not disclose surfactants other than SDS as the skin drying

agents and, in particular, the surfactants recited in newly added claims 18 and 19.

Therefore, the rejection over the RonaCare™ publication stands.

With respect to the rejection under 35 U.S.C. 103 and the ODP rejection, the Applicant argues: "Nothing in the references teaches or suggests the administration of ectoine or ectoine derivatives as defined in the claims to the skin in need of protection from high surfactant concentration, nor would one of ordinary skill in the art expect that such administration would provide such benefit to the skin." See pp. 10-11 of the reply. In response, Motitschke et al. teach treating aged, dry or irritated skin comprising administering to a patient in need of such treatment an effective amount of at least one ectoin together with a cosmetically acceptable carrier. Motitschke et al. also teach to a method of increasing or stabilizing the moisture content of a patient's skin, comprising administering to said patient an effective amount of at least one ectoin together with a cosmetically acceptable carrier. Further, Motitschke et al. teach that under normal conditions, the skin itself is capable of regulating its moisture content, but the skin is highly sensitive to chemical and physical factors. While Motitschke et al. do not explicitly teach the claimed "protecting the skin of a human patient from exogenous high surfactant concentration", both Geria and Idson connect skin dryness to the dehydration of the skin by conventional surfactants/detergents. See above. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Motitschke et al. such that to use it for protecting the skin from exogenous surfactants/detergents. One having ordinary skill

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in the art would have been motivated to do this because dry skin is caused by dehydration due to the detergent (surfactant) use as suggested by either Geria or Idson and the compositions of Motitschke et al. are capable of restoring the moisture level of the skin and treating or preventing skin dryness.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached at (571) 272-0629.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm, M.S., J.D.

Patent Examiner

11/25/06



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER